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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,277	03/01/2002	Graeme Cox	032505-010	6035

21839 7590 08/11/2005

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,277	COX ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11,.453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9,11-15,19,21,30,31,34,36 and 55-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,9,11-15,19,21,30,31,34 and 36* is/are allowed.

6)☒ Claim(s) *55-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2005 has been entered.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 55-57 and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (US 5,215,991).

Burke teaches a pharmaceutical composition comprising N,N-hexamethylene amiloride, or N, N-dimethyl amiloride. See the claims. Note it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161. As to the limitation in preamble, i.e., "oral" and "injectable" A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187

F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the preamble is not seen to further structurally limit the composition. Further, the sterlized composition disclosed by Burke would considered "injectable." As to the antiviral properties, note, any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990. See MPEP 2112.01.

Claims Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 55-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipton (US 5,506,231), in view of Benos et al. and Burke (US 5,215,991).

5. Lipton teaches a method for treating patient infected with HIV comprising administering to the patient a effective amount of Ca+ ion channel antagonist, see the Claims. amiloride is disclosed as a known Ca+ channel antagonist. See table 3 in column 4.

6. Lipton does not teach expressly the employment of amiloride, or the particular derivatives herein, for treating HIV infected patient.

7. However, Benos teaches that amiloride negates the effect of HIV toxic protein to the cells. See, particularly, the abstract. Burke teaches that amiloride and its analogues as herein recited are known to be similarly useful. See the entire document, particularly, the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use amiloride, or its analogue, such as HMA or DMA, as Ca+ channel antagonist for treating HIV infected patients.

A person of ordinary skill in the art would have been motivated to, to use amiloride, or its analogue, such as HMA or DMA, as Ca+ channel antagonist for treating HIV infected patients because amiloride is particularly known to negate the toxic effect introduced by HIV toxic protein, and the amiloride analogues, HMA and DMA, are known to be similarly useful as amiloride. As to the particular functional limitation, e.g., HIV replication, note the functional limitations herein do not carry patentable weight since the ultimate utility as herein claimed, treating HIV infected patient, is obvious to the prior art. Further, making a therapeutical agent into a well-known dosage forms, such as those suitable for oral or parenteral administration, is within the skill of artisans.

8. Claims 55-57, 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragoe Jr. et al. (US 4,085,211), in view of Burke (US 5,215,991).

9. Cragoe Jr. et al. teach amiloride compounds, including those recited herein, as eukalemic agents possessing diuretic and natriuretic properties. Cragoe Jr. et al. further teach pharmaceutical compositions comprising the amiloride compounds. See, particularly, the abstract, columns 1-2 and 22-23.

10. Cragoe Jr. et al. do not teach expressly a pharmaceutical composition comprising the amiloride compounds herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a pharmaceutical composition of the particular amiloride herein in the a dosage form suitable for oral administration, or for parenteral administration (injection).

A person of ordinary skill in the art would have been motivated to make a pharmaceutical composition of the particular amiloride herein in the a dosage form suitable for oral administration, or for parenteral administration (injection) because the compounds herein are known to be useful as therapeutical agents and are known to be made into a pharmaceutical composition. Making a known pharmaceutical agents into a particular well-known form, such as oral or injectable, would have been within the skill of artisan, and would have been obvious. As to the particular properties and intended use, note it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161. As to the antiviral properties, note, any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990. See MPEP 2112.01.

Response to the Arguments

Applicants' amendments and remarks submitted April 15, 2005 have been fully considered, but are not persuasive with respect to the rejections set forth above for reasons discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617